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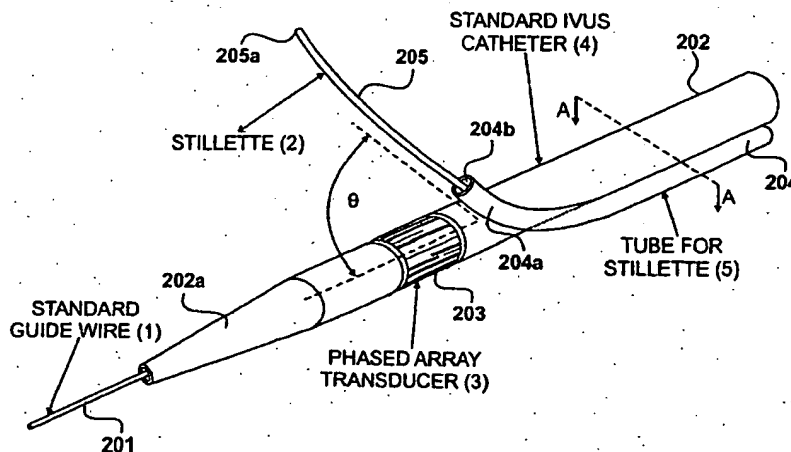
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(54) Title: **CORONARY BYPASS APPARATUS AND METHOD**



(57) Abstract: Apparatus for minimally invasively bypassing a body lumen, the apparatus comprising: a catheter having proximal and distal regions; an imaging transducer coupled to the distal region; and a cutting element adapted to form an opening in the body lumen, said coupled element coupled to the distal region, wherein the imaging transducer is adapted to enable a clinician to position said cutting element.

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Coronary Bypass Apparatus And Method

Background of the Invention

5 The present invention relates to a coronary bypass apparatus and method.

Coronary artery disease is a significant medical problem in the developed world and treatments include pharmaceutical therapies, surgical intervention and percutaneous angioplasty.

10 Surgical intervention uses a vessel harvested from the patient themselves and grafted onto the blocked coronary artery to bypass the obstruction. This is termed Coronary Artery Bypass Grafting (CABG). Usually this is a significant operation which involves opening up the chest cavity.

15 Percutaneous techniques use coronary catheters to open up the obstruction and require the catheter to cross through the obstruction. Such techniques are significantly less traumatic from the patient's point of view.

Description of the Related Art

20 The present invention is concerned with minimally invasive methods of performing CABG, which methods do not require such a major surgical operation as that discussed above.

One known technique takes advantage of the fact that many coronary arteries have a vein running parallel to the artery. An example is The Left Anterior Descending Coronary artery which has the Great Cardiac Vein in its vicinity.

25 This known technique diverts arterial blood into the vein by creating a conduit between the two in order to bypass the arterial blockage. Blood passing through the conduit either returns into the artery beyond the

blockage or through the vein perfuses the muscle with oxygenated blood. The return of the blood, the so-called venous return, is then via other routes. The advantage of this technique is that it can be performed percutaneously using catheters.

5 Examples of this known technique are disclosed in United States Patent Nos. 5,830,222 and 6,068,638.

 This prior art technique requires a separate ultrasound imaging catheter to enable the puncture to be made in the correct direction, namely towards the neighbouring vessel. In addition the vein which is proximal to the
10 conduit is blocked with a suitable plug in order to divert the high-pressure arterial blood into the distal region.

Brief Summary of the Invention

 The present invention is concerned with providing an improved
15 apparatus and method for bypassing a coronary blockage utilising the patient's adjacent vein as a bypass to that blockage.

 According to the present invention apparatus of the kind previously described for effecting an artery bypass utilising an adjacent vein is combined with imaging transducer in order to enable a clinician to accurately position
20 the means for creating a conduit between the artery and the adjacent vein.

 The apparatus preferably comprises a catheter with an imaging transducer. The imaging transducer may comprise, for example, an intravascular ultrasonic (IVUS) imaging transducer, a phased array IVUS transducer, a rotational or mechanical IVUS transducer, an Optical
25 Coherence Tomography (OCT) transducer, or a Magnetic Resonance Imaging (MRI) transducer.

 Where the imaging means comprises an imaging catheter the above

referred to combination could take a number of forms.

Firstly it could be achieved by having two separate catheters which are used one after the other. The first catheter carrying the ultrasonic transducer array at or near its distal end would be used to make the incision
5 in the wall of the artery and then the incision in the wall of the adjacent vein and the second catheter would then be used subsequently to create the conduit between the artery and the adjacent vein.

More particularly, the first catheter would incorporate a stillette (a wire with a pointed distal end) in order to pierce the wall of the artery and then the
10 wall of the adjacent vein.

The second catheter would incorporate means for enlarging the incision made in the walls of the artery and adjacent vein and would incorporate a stent which could then be delivered to the expanded apertures in the artery and the vein in order to create the conduit between the artery
15 and the vein.

Secondly it could be achieved by having a single catheter which combines the features of the two catheters referred to immediately above.

Brief Description of the Several Views of the Drawings

20 How the invention may be carried out will now be described by way of example only and with reference to the accompanying drawing in which:

Figure 1 illustrates a coronary bypass procedure using an adjacent vein;

Figure 2 is a perspective view showing the distal end of a first catheter
25 incorporating an imaging transducer;

Figure 3 is a partial cross-sectional view taken along the line A-A in *Figure 2*;

Figure 4 is a diagrammatic representation of the image of the catheter in use;

Figure 5 illustrates the use of the imaging catheter for making the incision in the artery and vein walls; and

5 *Figure 6* is a view similar to *Figure 4* and illustrating the endpoint of the second stage of the procedure employing the second type of catheter.

Best Mode for Carrying Out the Invention

10 A patient has a blockage **100** within a coronary artery **101** alongside which runs an existing vein **102**.

In order to bypass blockage **100** a first passage **103** is formed between the artery **101** and the vein **102** so that blood flowing in the artery **101** (as indicated by the arrows) can pass through the passage **103** and into the vein **102**.

15 This blood may then either be allowed to continue its flow through the vein **102** to perfuse the heart muscle with oxygenated blood, the venous return being via other routes within the patient's body, or the blood flow may pass through a second passage **104** formed between the vein **102** and the artery **101** in order to then continue its flow through the vein **101** having
20 bypassed the obstruction **100**.

This general technique is already known, the present invention being concerned with an apparatus and method for forming the passage **103**.

25 Essentially this apparatus and method involve the employment of two different and separate catheters that can be introduced into the patient's vascular system typically through an incision made in an artery in the patient's groin. This provides a method which is minimally invasive when compared with the major surgery required in carrying out Coronary Artery

Bypass Grafting (CABG).

The first step in this minimally invasive method is to insert into the patient's vascular system, and in particular the artery **101**, a standard guide wire **201** in the well-known way. The distal end of the guide wire **201** is positioned upstream of the blockage **100** in the vicinity of the location where it is desired to form the first conduit **103**.

The first catheter **202** is then slid down the guide wire **201** in known manner.

The first catheter **202** is an imaging catheter which has near its distal end **202a** a imaging transducer **203**. As this kind of intravascular ultrasonic catheter is already known it will not be described in any more detail.

Mounted on this intravascular imaging catheter **202** is a tube **204** which runs substantially the length of the catheter and through which a metal stillette **205** may be threaded. The stillette is a metal wire with a pointed distal end.

Thus one aspect of the present invention is the combination of the tube **204** mounted on the outside of an imaging catheter **202**.

The way in which this first catheter is employed will now be described with reference to *Figures 3 - 5* in which the same reference numerals have been used to designate those same items which appear in *Figures 1 and 2*.

It will be seen in *Figure 2* that the distal end of the tube **204** is at an angle to the axis of the body of the ultrasound catheter **202** whereas the main part of the tube **204** runs parallel to that axis. This angle to the axis of the catheter **202** is indicated at θ in *Figure 2*.

The purpose of the angling of the distal end **204a** of the tube **204** with respect to the axis of the catheter **202** is to enable the distal end of the stillette **205** to traverse the path indicated in *Figure 5*. A marker **401** can be

put on the image illustrated in *Figure 4* to indicate the intended route for the distal end of the stillette 205 in order to ensure that it pierces the arterial wall 101 and vein wall 102 at the correct locations.

5 The catheter 202 is rotated so that the opening 204b of the distal end of the tube 204 is pointing at the desired target area of the arterial wall 101 and the marker 401 aligns with both the artery 101 and the vein 102, the stillette 205 being aligned for the proper formation of the passage 103.

10 The stillette 205 which comprises a wire with a sharp tip 205a is then pushed down the tube 204 so that the tip 205a enters the arterial wall 101 and the marker 401 aligns with both the artery 101 and the vein 102, the stillette 205 being aligned for the proper formation of the passage 103. at the desired location of the first conduit 103.

15 Continued pushing of the stillette 205 results in the sharp tip 205a of the stillette passing through the matter 106 located between the artery 101 and the vein 102 and then piercing the wall 102b of the vein 102.

The distal tip 205a of the stillette 205 is in the imaging plane of the ultrasound array 203 thus enabling the correct position of the tip 205a to be confirmed from an examination of the image, as indicated in *Figure 4*.

20 Having positioned the distal tip 205a of the stillette 205 as indicated in *Figure 5* the first imaging catheter 202 can then be and is withdrawn from within the patient's artery by being pulled back along the guide wire 201 in the normal way.

25 The stillette wire 205 has to be rigid enough to puncture the artery wall 101b and the vein wall 102b but flexible enough to bend once the distal end 205a is within the lumen 102a of the vein 102, ie the pointed distal end 205a will not then continue and puncture the opposite wall of the vein 102.

These two competing requirements concerning the flexibility of the

distal end of the stillette **205** can be achieved in a number of ways.

One solution is to provide the stillette **205** with a rigid or semi-rigid tip **205a** which could be about 3-4mm in length, there then being a flexible portion immediately adjacent the semi-rigid tip.

5 With this arrangement the flexible portion would be constrained within the delivery tube **204a**, thus preventing it from bending, with only the semi-rigid tip protruding from the tube **204**.

10 Once the semi-rigid tip has pierced the wall of the artery **101** and the wall of the vein **102** and as a result the flexible portion adjacent the semi-rigid tip is now outside the distal end **204a** of the delivery tube **204** the distal end of the stillette can bend within the lumen **102a** of the vein **102** thus ensuring that there is no danger of the pointed end **205a** of the stillette puncturing the far wall of the vein **102**.

15 A second way of overcoming the problem referred to is to construct the stillette as a hypodermic tube as is well known to those skilled in the art.

 After the hypodermic tube has penetrated into the lumen of the vein **102** a separate flexible guide wire is inserted through the inner lumen of the hypodermic tube, this guide wire being a standard guide wire and therefore flexible and not likely to penetrate the wall of the vein **102**.

20 An advantage of using the second solution, namely the hypodermic tube, is that contrast liquid can be injected down the hypodermic tube so that once the tube enters the vein lumen **102a** the contrast liquid will be seen on the fluoroscopy display to indicate that access from the lumen **101a** of the artery **101** into the lumen **102a** of the vein **102** has been achieved.

25 After the first imaging catheter **202** has been withdrawn from within the patient the stillette **205** is left within the patient's artery **101** with its proximal end outside the patient and accessible by the clinician and its distal end

located within the lumen of the patient's vein 102.

Thus the stillette 205 can then be used in effect as a guide wire for introducing the distal end of a second catheter into the conduit 103 formed between the patient's artery 101 and the patient's vein 102.

5 The essence of the second catheter is that it carries an expandable stent at or near its distal end so that the stent 601 can be delivered to its operative position as shown in *Figure 6*.

10 The stillette is used as a guide wire over which the stent catheter is advanced. However, the stent is delivered in a collapsed delivery configuration, and then expanded in place to an expanded deployed configuration, for example, with a balloon catheter, or through self-expansion. Thus, the second catheter preferably comprises a balloon catheter when a balloon-expandable stent is used, and a self-expandable stent delivery system when a self-expanding stent is used.

15 The stent acts as a conduit between the patient's artery 101 and the patient's vein 102. Additionally, or alternatively the stent may act as a plug or barrier within the lumen 102a of the vein 102 to prevent the flow of blood from the area B to the area C, or vice versa, as indicated in *Figure 6*.

20 The stent 601 may have a number of known constructions, these all essentially consisting of an expandable lattice or coiled spring-like structure whereby the stent can either have a retracted configuration when it is mounted on the delivery catheter (not shown) or is then capable of being expanded radially outwardly to form what is essentially a latticework tube as indicated in *Figure 6*.

25 Preferably the stent is also provided with a flexible cover (not shown) which would be essentially in the form of a tube coupled to the stent so that the stent will provide an effective lining to the conduit between the lumen of

the patient's artery **101** and the lumen of the patient's vein **102**.

The delivery system for the stent could take a number of forms ie the catheter on which the stent is initially mounted could take a number of forms.

5 In one embodiment the catheter would be provided with a balloon around which the unextended stent is mounted when the second catheter is first inserted into the patient's artery **101**.

With this arrangement when the stent is in the target area as shown in *Figure 6* the balloon is expanded in the normal way typically by introducing into it, from the proximal end of the catheter, a saline solution. Expansion of
10 the balloon converts the stent from its retracted to its expanded position as shown in *Figure 6*. Optionally the stent would be provided with a protective sheath to avoid its dislodgement as the distal end of the second catheter is pushed along the patient's artery **101** to bring the stent into the target area shown in *Figure 6*.

15 In another embodiment the stent is self-expandable and is mounted on a sheath-based stent delivery system in known manner, such as the JOSENT Self-X stent and delivery system marketed by JOMED NV of Amsterdam, The Netherlands.

In order to avoid any risk of the stent being dislodged from its
20 operative position, as shown in *Figure 6*, the proximal end of the stent may protrude into the coronary artery **101** by, for example, 0.5 mm, and this protruding portion expanded so that the narrowest cross-section of the stent is located between the patient's artery **101** and the patient's vein **102**.

Claims

1. Apparatus for minimally invasively bypassing a body lumen, the apparatus comprising:

a catheter having proximal and distal regions;

an imaging transducer coupled to the distal region; and

a cutting element adapted to form an opening in the body lumen, said coupled element coupled to the distal region, wherein

the imaging transducer is adapted to enable a clinician to position said cutting element.

2. The apparatus of claim 1, wherein the cutting element comprises a tube coupled to the distal region of the catheter.

3. The apparatus of claim 2, wherein the cutting element further comprises a stillette adapted for passage through the tube, such that the stillette projects from the distal end of the tube.

4. The apparatus of claim 3 wherein the distal end of the tube is disposed substantially within an imaging plane of the imaging transducer.

5. The apparatus of claim 3, wherein a distal end of the stillette is at least semi-rigid.

6. The apparatus of claim 5, wherein a portion of the stillette adjacent its distal end is flexible.

7. The apparatus of claim 3, wherein a distal end of the stillette

comprises a hypodermic needle.

8. The apparatus of claim 1 further comprising an expandable stent coupled to the catheter.

5

9. The apparatus of claim 8, wherein the expandable stent comprises a stent chosen from the group consisting of a balloon-expandable stents, self-expanding stents, wire mesh stents, and bi-stable stents.

10

10. The apparatus of claim 8 further comprising an expander adapted to expand the stent.

15

11. The apparatus of claim 10, wherein the expander comprises an expander chosen from the group consisting of a balloon, and a self-expanding stent delivery system.

20

12. the apparatus of claim 1, wherein the imaging transducer is chosen from the group consisting of intravascular ultrasonic imaging transducers, phased array intravascular ultrasonic imaging transducers, rotational intravascular ultrasonic imaging transducers, mechanical intravascular ultrasonic imaging transducers, optical coherence tomography imaging transducers, and magnetic resonance imaging transducers.

25

13. A method for aligning an element of a catheter having an imaging transducer with a target site of a body lumen, the method comprising:

marking the radial position of the element relative to the imaging

transducer in images obtained from the imaging transducer; and
aligning the marking of the radial position with the target site in the
images obtained from the imaging transducer.

5 **14.** the method of claim 13, wherein the element comprises a
cutting element.

15. The method of claim 14 further comprising forming an opening
in the target site with the cutting element.

10 **16.** The method of claim 13, wherein aligning the marking
comprises rotating the catheter.

17. The method of claim 13, wherein aligning the marking
15 comprises advancing or retracting the catheter with respect to the target site.

18. The method of claim 13, wherein the imaging transducer is
chosen from the group consisting of intravascular ultrasonic imaging
transducers, phased array intravascular ultrasonic imaging transducers,
20 rotational intravascular ultrasonic imaging transducers, mechanical
intravascular ultrasonic imaging transducers, optical coherence tomography
imaging transducers, and magnetic resonance imaging transducers.

19. A method of detecting formation of a passage from a patient's
25 vein during minimally invasive bypass, the method comprising:
providing a hypodermic tube;
percutaneously advancing the tube to a target site within the patient's

artery;

injecting contrast medium through the tube;

advancing the tube through the target site into the patient's vein,

thereby forming a passage between the patient's vein;

5 and detecting the contrast agent within the patient's vein.

20. The method of claim 19, wherein detecting the contrast agent comprises fluoroscopically detecting the contrast agent.

10 21. The method of claim 19, wherein advancing the tube through the target site further comprises aligning the tube with the target site using an imaging modality.

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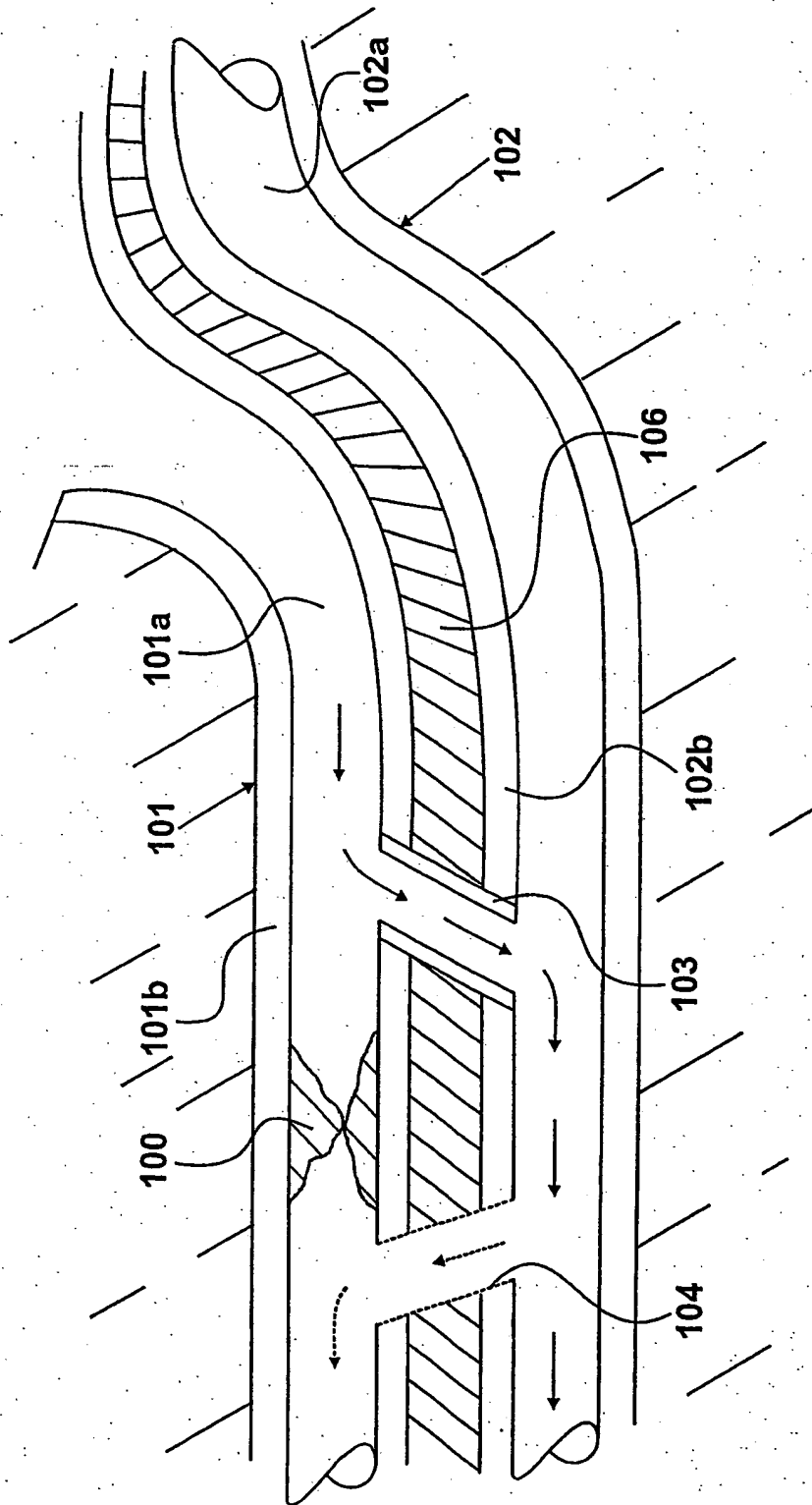


Figure 1

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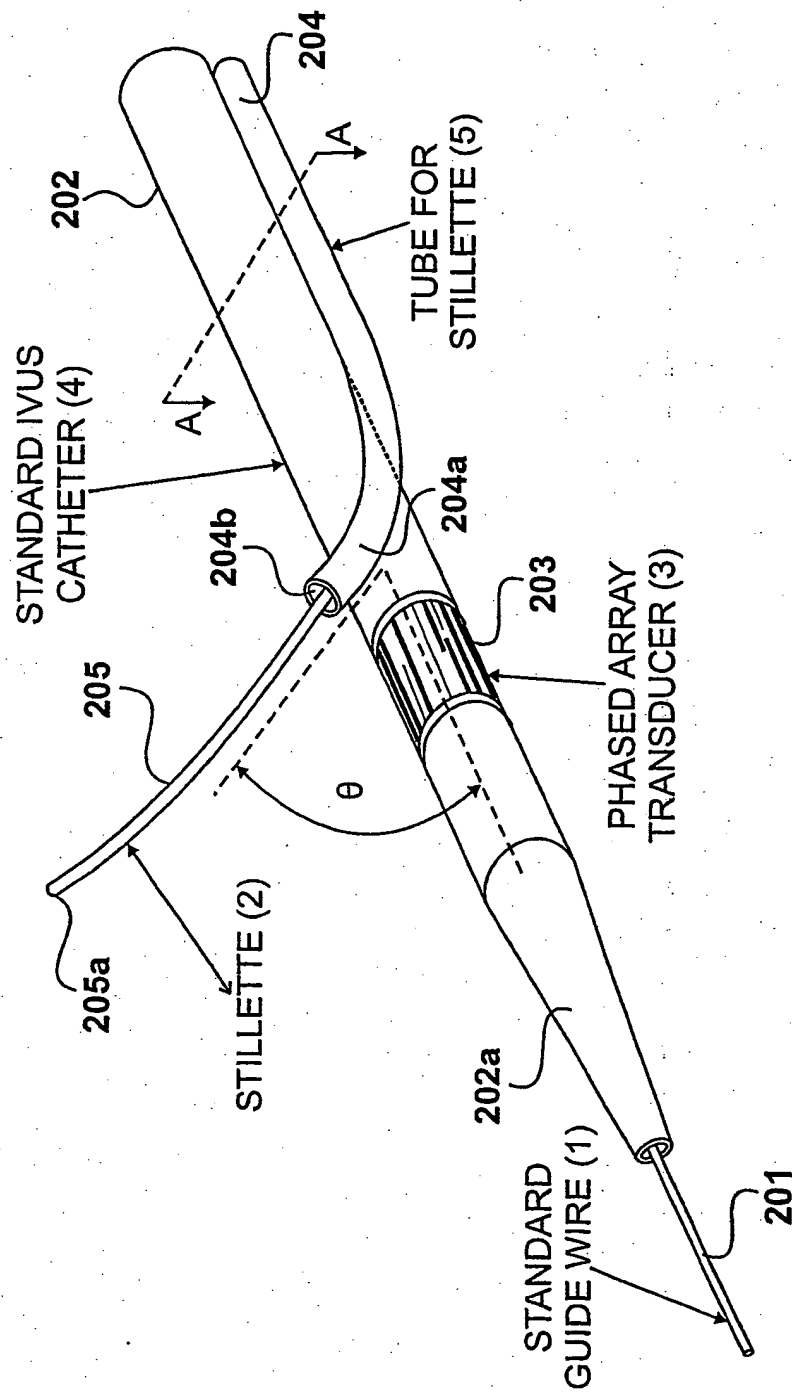


Figure 2

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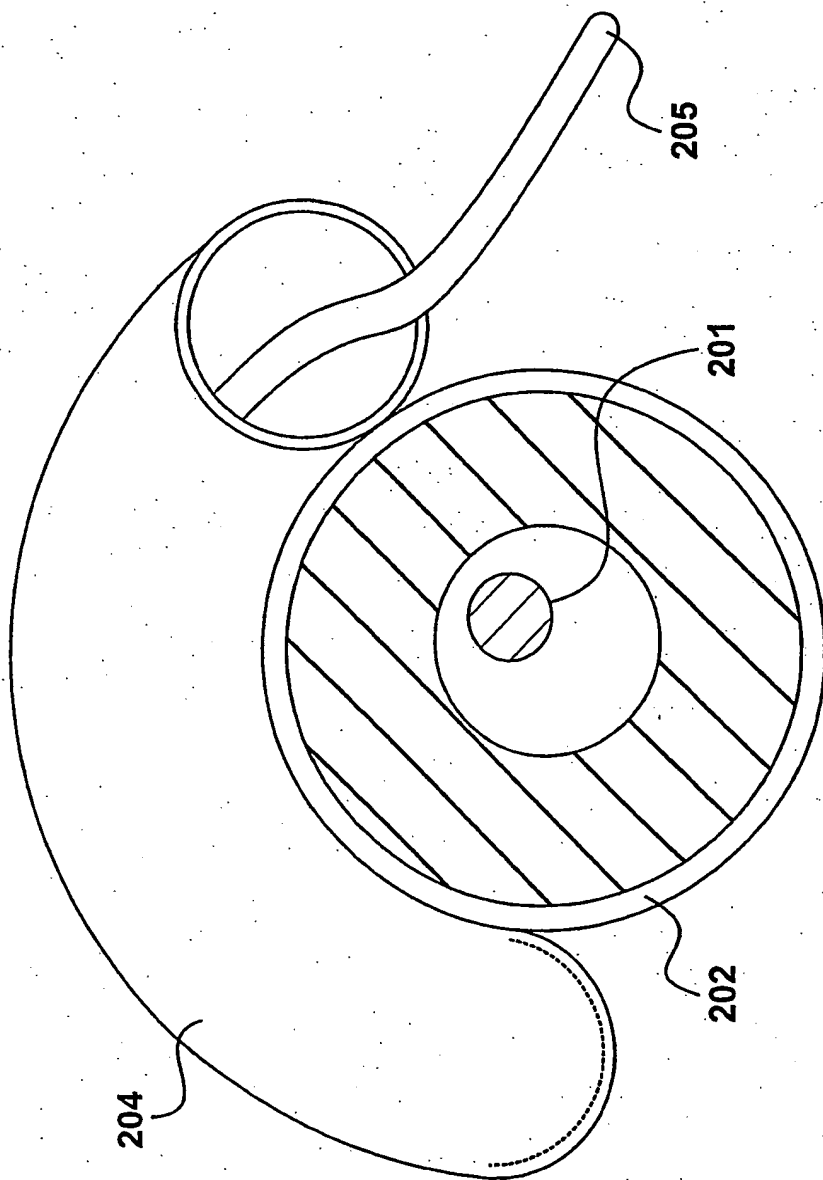
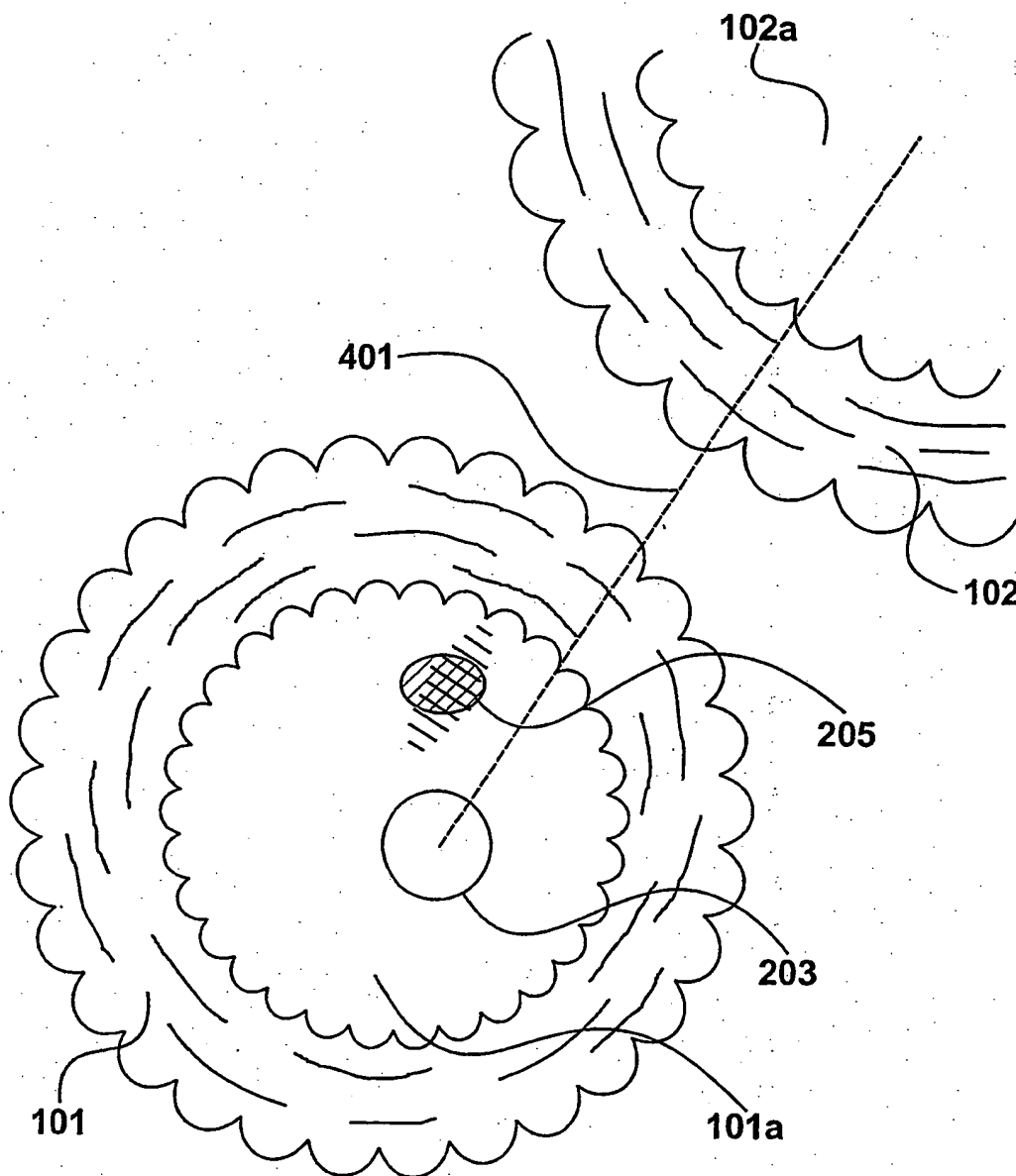


Figure 3

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*Figure 4*

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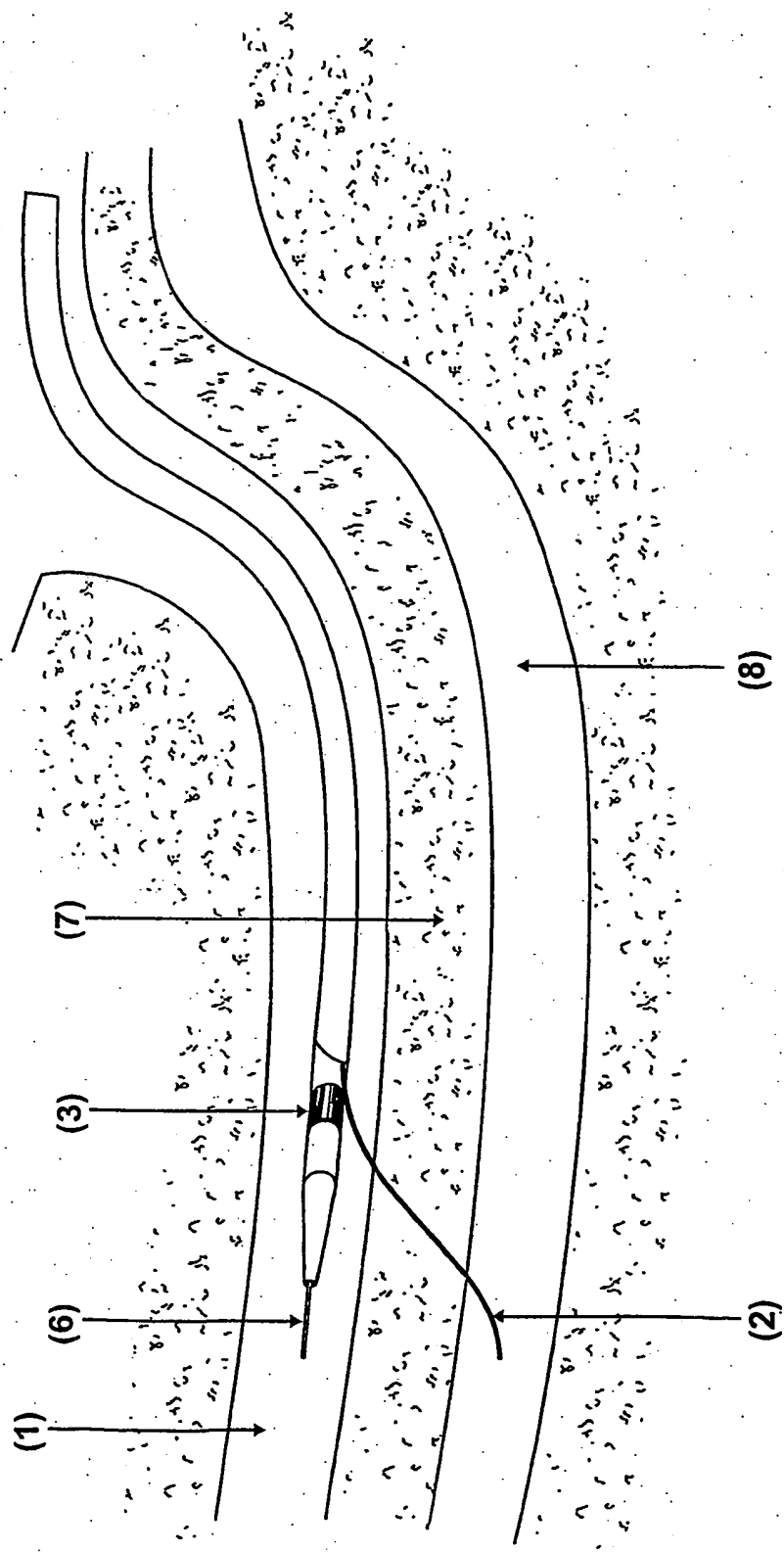


Figure 5

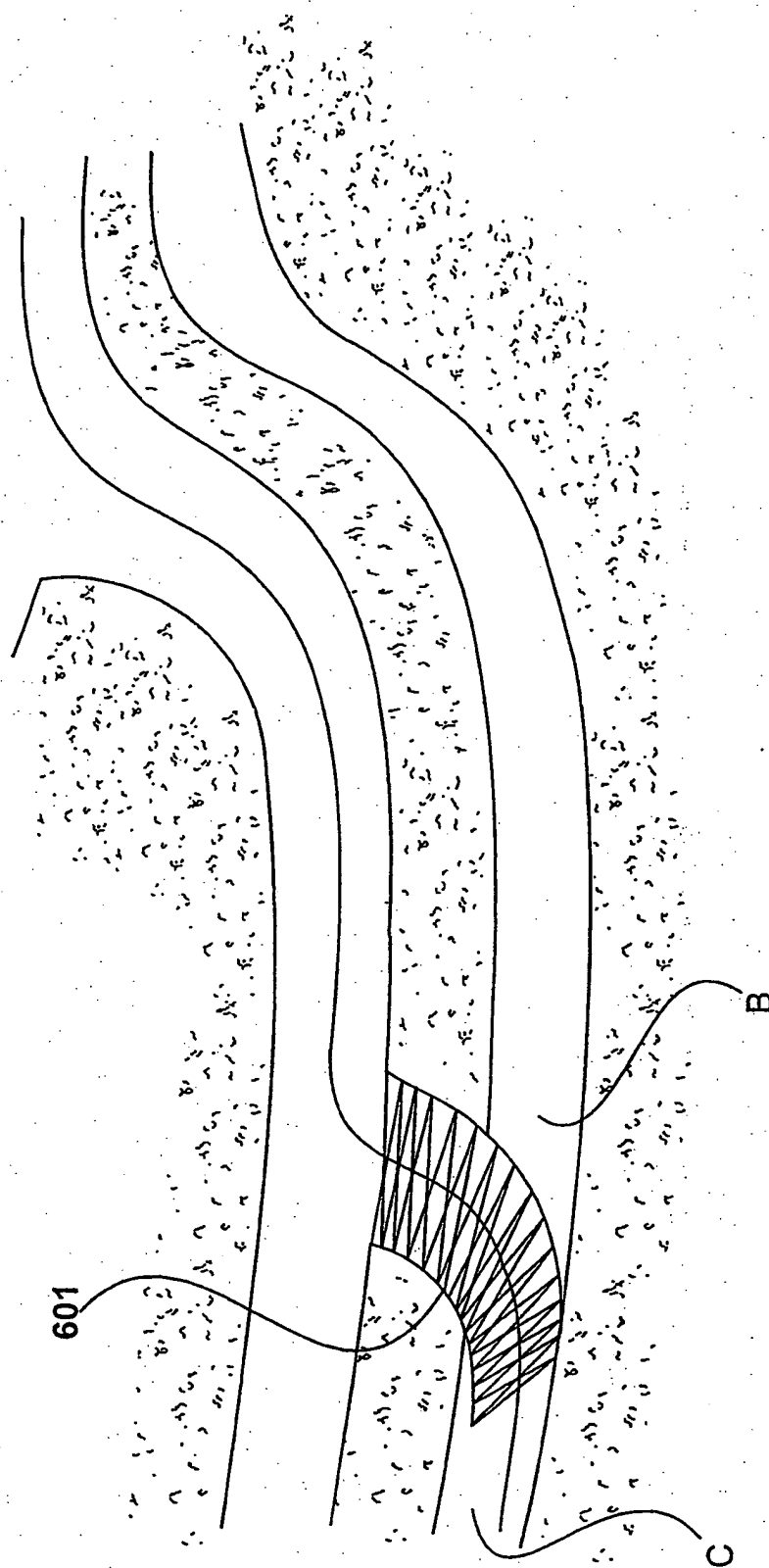


Figure 6

INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

19 December 2001

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INTERNATIONAL SEARCH REPORT

In: International Application No

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